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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/727,893

12/03/2003

Charles P. Meader

EQIN.01USUI

6744

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05/17/2006

COCHRAN FREUND & YOUNG LLC
2026 CARIBOU DR
SUITE 200
FORT COLLINS, CO 80525

EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,893

Applicant(s)

MEADER ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 18-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-17 is/are rejected.
- 7) ☒ Claim(s) 9, 12 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/04/12/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group II, claims 9 – 17 in the reply filed on April 27, 2006 is acknowledged.

Claims 1 – 8 and 18 – 25 are withdrawn, as they are drawn to non elected subject matter.

Claims 9 – 17 have been considered on the merits.

Claim Objections

2. Claims 9, 12 and 16 are objected to because of the following informalities:

In claim 9, line 3, "form" should be spelled "from".

In claim 9, line 3, the second recitation of "that" may be replaced with "and" to more clearly identify that the synovial fluid is processed, not the donor animal.

In claim 12, line 3, "that" should be replaced with "than" to be grammatically correct.

Claims 16 should end with a period. (MPEP 608.01(m))

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 9 – 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Rulcker et al. (1981).

Applicant claims a method for treating a joint malady of an animal, the method comprising intraarticularly injecting a replacement fluid in the joint space of the animal, wherein the replacement fluid comprises synovial fluid harvested from other animals, and has been processed, lyophilized, packaged and reconstituted. Applicant additionally claims a method for treating a joint malady of an animal, the method comprising intraarticularly injecting a purified synovial fluid in the joint space of the animal, wherein the purified synovial fluid is made by collecting synovial fluid from a donor animal; removing impurities; lyophilizing the purified fluid; and reconstituting the fluid to about the original volume. The step of collecting comprises selecting a donor joint, injecting a needle with syringe into the joint, aspirating fluid joint contents, and preserving the fluid joint contents; the step of preserving comprises freezing at less than 0C; the step of removing impurities comprises separating higher density particles via centrifuge, removing higher density particles from the supernate, filtering the supernate to remove .45 mm particles; the step of lyophilizing comprises stabilizing the purified synovial fluid, freezing at about -45C, reducing air pressure to less than 50 microns of mercury, maintaining the fluid at -35C for 72 hours, 0C for 12 hours and 25C for 12 hours and further placing the purified fluid under vacuum. The method further comprises providing the lyophilized fluid to users wherein providing comprises providing the fluid in a vacuum sealed vial for reconstitution within the vial to produce a single use injection.

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Rulcker teaches a method for treating joints of an animal, wherein the method comprises injecting synovial fluid obtained from another animal into the synovial joint of the animal in need thereof (p.264).

Although Rulcker does not teach the method wherein the synovial fluid is made by the claimed process, these limitations are considered to be product by process type limitations. Thus, the patentability of a product, and the method that uses the product, does not depend on the method of producing the product (i.e., the purified synovial fluid). If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. In the instant case, the method of the prior art is the same as that claimed. Thus the methods differ only in how the synovial fluid is produced. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 11, 2006
AU 1651

A handwritten signature in black ink, appearing to read 'R Davis', with a stylized, cursive script.

RUTH A. DAVIS
PATENT EXAMINER